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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,431	06/05/2001	Karl Kolter	51497	5147

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EXAMINER	
TUBA A, BLESSING M	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/18/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/873,431	Applicant(s) KOLTER ET AL	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1- 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner acknowledges receipt of paper numbers 2, 3 and 6 filed 06/05/01 and paper number 5 filed 0401/02. Applicants in response to the election requirement elected, without traverse, polyethylene glycol of claim 16, hydroxypropyl cellulose of claim 14, analgesic of claim 20 and vitamins of claim 25. Accordingly, examination is directed to the elected species.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 16 recites polyvinylpyrrolidone derivatives and claim 15 recites derivatives, which are not described in the written disclosure.

For the rejection under 35 U.S.C. 112, first paragraph, the following factors are considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

1) Nature of invention.

2) Amount of direction and guidance provided by the inventor.

3) Existence of working examples

4) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Nature of the invention: The present invention is directed to sustained release composition and the process of making said composition where the composition comprises a mixture of polyvinyl acetate and polyvinylpyrrolidone and where the process comprises granulating the composition by heating the composition to a temperature of from 40 °C to 130 °C. The disclosure does not describe what "polyvinylpyrrolidones and derivatives" are. The specification neither says what "polyvinylpyrrolidones and derivatives" are nor provides a list of "polyvinylpyrrolidones and derivatives" that are applicable in the invention.

Existence of working examples and Amount of direction and guidance provided by the inventor: There is no working example of said composition or how said composition comprising "polyvinylpyrrolidones and derivatives" are made except for a process of making compositions comprising polyvinylpyrrolidone. The guidance provided is to process of making compositions that contain polyvinylpyrrolidone. Since there is no description of what the "polyvinylpyrrolidones and derivatives" are, and since there are no working examples of compositions that contain the "polyvinylpyrrolidones and derivatives," the guidance provided by the inventors is not adequate and therefore, extrapolating the disclosed invention to the claimed invention would be burdensome to do by one skilled in the art. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by the applicants. In the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the

applicants. However, the amount of direction and guidance provided by the applicants is limited to polyethylene glycol and polyethylene glycol methyl ether.

The quantity of experimentation required to use the claimed invention, based on applicants' disclosure would be undue burden because, one of ordinary skill in the art would have to determine which compounds are "polyvinylpyrrolidones and derivatives" and experiment with all possible candidates that fall within the context of "polyvinylpyrrolidones and derivatives" in order to determine those derivatives that would work in the block polymer. It appears that applicants are claiming known and yet to be discovered derivatives of polyvinylpyrrolidones.

It is recommended that claim 16 be amended to delete the "polyvinylpyrrolidones and derivatives" which are not described in the written disclosure.

4. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 15 and 16, the term derivatives in lines 7 and 4 respectively is indefinite because the claims do not define what the derivatives are.

Regarding claims 8, 14 and 15, the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 16, the term "preferably" is deemed to be indefinite since it is unclear whether the components recited after the said term are indeed limitations. Further more, the use of the term in a Markush language is improper.

Regarding claims 1and 17, the term "other", in lines 8 and 7 respectively, is deemed indefinite because it is not clear what is included or excluded from the term and whether the phrase following the term is indeed a limitation.

Regarding claims 1, 7 and 17 the term "conventional", in lines 8, 1 and 7 respectively, is a relative term that does not allow one to determine the breath of the claims. What is conventional today may not be conventional tomorrow.

Regarding claim 10, it is confusing how the production process is "both continuously and batchwise."

Regarding claim 11, it is not clear how processing the granules takes place "both in the hot state and in the cold state."

Regarding claims 1 and 17, "where appropriate," in sections c) and d) of both claims is confusing. When or where is it appropriate or not appropriate to include excipients and water-soluble polymers?

Regarding claim 12, the expression "it is possible" is not a positive limitation because it is not clear if what comes after the expression is part of the claim.

Claims 19 and 20 recite the limitation "active pharmaceutical ingredients" in lines 2. There is insufficient antecedent basis for this limitation in the claim. Claims 19 and 20 appear to depend from claim 18 that recites "active pharmaceutical ingredients" in lines 3 and 4.

Claim 3 recites the limitation "the active ingredient : release-slowing agent" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite "release-slowing agent."

Claim 3 recites the limitation "the combination" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the water-soluble highly swelling substances" in line 2. There is insufficient antecedent basis for this limitation in the claim.

It is suggested that in claims 16 and 20, after group in line 2, ---consisting--- be inserted in order for the claims to conform to proper Markush language of "selected from the group consisting of."

In line 17 of claims 20, after antagonist, ---and--- or ---or--- may be inserted in order for the claim to conform to proper Markush language.

5. Claim 25 provides for the use of "the oral dosage forms", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 25 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goertz et al. (US 4,801,460) and Ortega (US 4,837,032) in combination.

Goertz teaches a process of preparing sustained release theophylline composition where the process comprises heating a mixture of N-vinylpyrrolidone and vinyl acetate and theophylline at a temperature of 120 °C (examples 1 and 3). The composition is extruded and pressed into oblong tablets (examples 1 and 3). Goertz teaches that vinylpyrrolidone is a polymer (column 1, line 7) and that the binders are polymeric (and column 5, line 6). The composition further comprises lubricants (column 2, lines 17-31).

Goertz is silent on the presence of hydroxypropylcellulose in the composition. But Ortega teaches a sustained release composition comprising theophylline, polyvinyl acetate and polyvinylpyrrolidone, cellulose acetate phthalate and optionally lubricant (abstract). Ortega specifically teaches that water-soluble polymers or gel forming polymers are used in the composition and the water-soluble polymers or gel forming polymers in Ortega are polyvinylpyrrolidone and cellulose derivatives such as hydroxypropylcellulose (column 3, lines 49-53). Thus Ortega suggests that theophylline composition comprising polyvinyl acetate and hydroxypropylcellulose can be prepared.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Goertz in combination with the teachings of Ortega. One having ordinary skill in the art would have been motivated to prepare a third composition comprising theophylline by combining the compositions of Goertz and Ortega because "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be

useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). In the present case, theophylline compositions are prepared. Expectation of success is high because the individual prior art teaches theophylline composition and the expected result from combining the individual compositions to prepare a third theophylline composition is a composition that comprises polyvinylpyrrolidone, polyvinyl acetate and hydroxypropylcellulose.

A recitation of molecular weight and particle size is not critical over the prior art in the absence of a showing.

8. Claims 17- 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda et al. (US 5,389,380) and Goertz et al. (4,801,460) in combination.

Noda teaches a composition comprising active ingredients, excipients such as lactose, sucrose, sorbitol and mannitol and higher fatty acid or polyethylene glycol (column 4, lines 43-47 and column 5, lines 63-65). Some of the active ingredients are theophylline, vitamins and analgesic.

Goertz teaches a process of preparing sustained release theophylline composition where the process comprises heating a mixture of N-vinylpyrrolidone and vinyl acetate and theophylline at a temperature of 120 °C (examples 1 and 3). The composition is extruded and pressed into oblong tablets (examples 1 and 3). Goertz teaches that vinylpyrrolidone is a polymer (column 1, line 7) and that the binders are polymeric (and column 5, line 6). The composition further comprises lubricants (column 2, lines 17-31).

Theophylline active agent is common to the compositions of both prior art. And because the compositions in the individual prior art have a common active ingredient, combined compositions can be prepared from the individual compositions. Noda does not teach a mixture of N-vinylpyrrolidone and vinyl acetate with theophylline or with analgesic or with vitamin. But Goertz teaches a mixture of N-vinylpyrrolidone and vinyl acetate with theophylline.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Noda in combination with the teaching of Goertz. One having ordinary skill in the art would have been motivated to prepare composition of Noda comprising excipients such as lactose, sucrose, sorbitol and mannitol and higher fatty acid or polyethylene glycol and active ingredients selected from theophylline, vitamins and analgesic in a mixture of N-vinylpyrrolidone and vinyl acetate since Goertz t prepared a composition comprising theophylline and a mixture of N-vinylpyrrolidone and vinyl acetate. Expectation of success is high because the individual prior art teaches individual compositions comprising theophylline.

Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
June 17, 2002